

IN THE UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF TEXAS  
(MARSHALL DIVISION)

FILED-CLERK  
U.S. DISTRICT COURT

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TX EASTERN-MARSHALL

JANIS GRAHAM and JOHN GRAHAM,

Plaintiffs,

vs

MERCK & CO., INC.

Defendant.

Civil Action No. **2-07 CV-318**

BY

**LED**

**JURY TRIAL DEMANDED**

**PLAINTIFFS' ORIGINAL COMPLAINT**

Plaintiffs JANIS GRAHAM and JOHN GRAHAM bring this action against Defendant MERCK & CO., INC., and would respectfully show the court the following:

**I. PARTIES**

1. This is an action for damages to Plaintiffs JANIS GRAHAM and JOHN GRAHAM arising from Defendant MERCK & CO., INC.'s respective design, manufacture, sale, testing, marketing, advertising, promotion, and/or distribution of the unsafe medications Alendronate Sodium, trade name FOSAMAX® ("FOSAMAX").

2. Plaintiffs, JANIS GRAHAM and JOHN GRAHAM (hereinafter "Plaintiffs") was and still are residents of Waskom, Harrison County, Texas

3. At all times relevant herein, Merck & Co., Inc. (hereinafter "Merck"), was and is an American pharmaceutical company incorporated under the laws of the State of New Jersey with its principal place of business at One Merck Drive, P. O. Box 100, Whitehouse Station, New Jersey 08889-0100. Defendant was and is in the business of profiting from the design, manufacture, marketing, distribution and/or sales of the brand-name prescription drug

FOSAMAX in Texas and nationwide.

## **II. GENERAL BACKGROUND AND OVERVIEW OF CLAIMS**

4. This is an action for damages suffered by Plaintiff as a direct and proximate result of the Defendant's negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of the pharmaceutical product known as Fosamax (hereinafter referred to as "Fosamax" or "the subject product").

5. At all times material hereto, Defendant designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold Fosamax for the prevention and treatment of osteoporosis as well as the treatment of Paget's disease.

6. As a result of the defective nature of Fosamax, those persons who were prescribed and ingested Fosamax, including Plaintiff, have suffered and continue to suffer severe and permanent injuries, including osteonecrosis of the jaw.

7. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and death.

8. Defendant knew of the significant risk of dental and oral complications caused by ingestion of Fosamax, but Defendant did not adequately and sufficiently warn consumers, including Plaintiff, or the medical community, of such risks.

9. Defendant failed to conduct adequate post-marketing surveillance of Fosamax after it began marketing, advertising, distributing and selling the product.

10. Consumers, including Plaintiff, who have used Fosamax for treatment of osteoporosis, have several alternative safer products available to treat this condition.

11. As a result of Defendant's actions, Plaintiff and her prescribing physicians

were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations.

12. As a direct result, Plaintiff was prescribed and ingested Fosamax and has been permanently and severely injured. Plaintiff requires and will require ongoing medical care and treatment.

13. Consequently, Plaintiff seeks actual and punitive damages for her injuries resulting from her ingestion of Fosamax, which has caused and will continue to cause Plaintiff to suffer pain, mental anguish and other injuries, as well as to incur significant expenses.

### **III. JURISDICTION AND VENUE**

14. This is an action for damages, which exceeds Seventy-Five Thousand Dollars (\$75,000.000)

15. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C.A. § 1332 (diversity jurisdiction) because the amount in controversy exceeds \$75,000.00, and because there is complete diversity of citizenship between Plaintiffs and Defendants.

16. Venue is proper in this United States Judicial District pursuant to 28 U.S.C.A. § 1391, in that Plaintiffs reside, used Fosamax, and suffered injury, in Harrison County, Texas; and Defendants marketed, advertised and distributed the dangerous product in the district, thereby receiving substantial financial benefit and profits the dangerous product in this district, and reside in this district under 28 U.S.C.A. § 1391(c).

17. At all relevant times herein, Defendants were in the business of designing, manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting and selling their products, FOSAMAX. Defendants at all times relevant hereto designed, developed, manufactured, promoted, marketed, distributed, tested, warranted and sold in interstate commerce (Texas) the aforementioned prescription drugs. Defendants do substantial business in the State of Texas and within this Federal Judicial District, advertise in this district, receive substantial compensation and profits from sales of FOSAMAX in this District, and made material omissions and misrepresentations and breaches of warranties in this District so as to subject them to *in personam* jurisdiction in this District. In engaging in the conduct alleged herein each Defendant acted as the agent for each of the other Defendants, or those Defendant's predecessors in interest.

#### **IV. FACTUAL BACKGROUND REGARDING PLAINTIFF**

18. Plaintiff JANIS GRAHAM was prescribed and began taking FOSAMAX in July of 2001 and continued taking FOSAMAX until May of 2004.

19. Plaintiff used Fosamax as prescribed and for the purpose and in the manner for which it was normally intended.

20. Plaintiff could not by the exercise of reasonable care discover the defective nature and perceive the danger of Fosamax.

21. As a direct and proximate result of using Fosamax, Plaintiff was diagnosed with osteonecrosis of the jaw on or about June 13, 2003.

22. Plaintiff, as a direct and proximate result of using Fosamax, suffered severe

mental and physical pain and suffering and has sustained permanent injuries and emotional distress.

23. Plaintiff would not have used Fosamax had Defendant properly disclosed the risks associated with the drug.

**V. FACTUAL BACKGROUND REGARDING DEFENDANT  
and FOSAMAX**

24. In September 1995, Fosamax was approved for marketing and sale in the treatment of osteoporosis and Paget's disease.

25. Fosamax falls within a class of drugs known as bisphosphonates, which are used for treating bone conditions such as osteoporosis and Paget's disease. Other drugs within this class such as Aredia and Zometa are also used as chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis.

26. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia); ibandronate (Bondronat); and alendronate (Fosamax). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid). Alendronate, like the others, contains a nitrogen atom, whereas etridonate, clodronate, and tiludronate do not. The Physician's Desk Reference ("PDR") listing for Fosamax confirms that the molecule contains a nitrogen atom.

27. Recent studies report the frequent and common occurrence of osteonecrosis of the jaw within the nitrogenous bisphosphonates used for chemotherapy.

28. Shortly after Defendant began selling Fosamax, reports of osteonecrosis of

the jaw and other dental complications among users began surfacing, indicating that Fosamax shared the class effects of the other nitrogenous bisphosphonates.

29. Merck knew or should have known that bisphosphonates, including Fosamax, inhibit endothelial cell function. Similarly, Merck knew or should have known that bisphosphonates also inhibit vascularization of the affected area and induce ischemic changes specific to patients mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.

30. Merck also knew or should have known that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can develop into a non-healing wound. That in turn can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

31. Despite this knowledge, Defendant failed to implement further study risk of osteonecrosis of the jaw relative to Fosamax. Rather than evaluating and verifying the safety of Fosamax with respect to osteonecrosis of the jaw, Defendant proposed further uses of Fosamax, such as Fosamax-D, and sought to extend the exclusivity period of Fosamax through 2018.

32. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and death.

33. Since Fosamax was released, the FDA has received a number of reports osteonecrosis of the jaw among users of Fosamax.

34. On August 25, 2004, the United States Food and Drug Administration ("FDA") posted its ODS Postmarketing Safety Review on bisphosphonates - - specifically pamidronate (Aredia), zoledronic acid (Zometa), risedronate (Actonel), and alendronate

(Fosamax) This was an epidemiologic review of the FDA adverse events database conducted by the FDA's Division of Drug Risk Evaluation.

35. As a result of the FDA Review, the FDA observed that the risk of osteonecrosis of the jaw was not confined to bisphosphonates used for chemotherapy. The FDA's review indicated that the osteonecrosis of the jaw was a class effect which specifically extended to the oral bisphosphonate, Fosamax.

36. As a result, the FDA recommended and stated that the labeling for Fosamax should be amended by Merck to specifically warn about the risk of osteonecrosis of the jaw. Merck has refused to accede to the FDA's request and, to this day, still does not warn of the risk of osteonecrosis of the jaw in its Fosamax labeling in the warnings section.

37. Rather than warn patients, and despite knowledge known by Defendant about increased risk of osteonecrosis of the jaw on patients using Fosamax, Defendant continues to defend Fosamax and minimize unfavorable findings.

38. Fosamax is one of Defendant's top selling drugs, which average more than \$3 billion a year in sales.

39. As with its reported and acknowledged side effects concerning irritation, erosion, and inflammation of the upper gastrointestinal tract, Merck knew or should have known that Fosamax, as a nitrogenous bisphosphonate, shared a similar adverse event profile to the other nitrogenous bisphosphonates.

40. Despite this knowledge, Defendant failed to implement further study of the risk of osteonecrosis of the jaw relative to Fosamax. Rather than evaluating and verifying the safety of Fosamax with respect to osteonecrosis of the jaw, Defendant proposed further uses of

Fosamax, such as Fosamax -D, and sought to extend the exclusivity period of Fosamax through 2018.

41. Fosamax remains in the body for years after ingestion but provides minimal benefits for preventing bone fractures. Additionally, if taken over long periods of time, the drug can make bones more brittle and increase the risk of fracture.

42. Dentists are now being advised by state dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient taking Fosamax.

43. Rather than warn patients and the medical community, and despite knowledge by Defendant of increased risk of osteonecrosis of the jaw on patients using Fosamax, Defendant continued and continues to defend and aggressively market Fosamax, while downplaying any unfavorable findings and overstating its benefits.

44. Fosamax is now the world's top-selling bisphosphonate and Defendant's second-best selling drug, with more than 22 million prescriptions in 2005 amounting to \$3.2 billion in sales.

## **VI. EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS**

45. The running of any statute of limitations has been tolled by reason of Defendant's fraudulent concealment. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and her prescribing physician the true risks associated with taking Fosamax.

46. As a result of Defendant's actions, Plaintiff and, upon information and



belief, her prescribing physician were unaware, and could not reasonably know or have learned through reasonable diligence that she had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendant's acts and omissions.

47. Furthermore, Defendant is estopped from relying on any statute of limitations because of their fraudulent concealment of the true character, quality and nature of Fosamax. Defendant was under a duty to disclose the true character, quality and nature of Fosamax because this was non-public information over which the Defendant had and continues to have exclusive control, and because the Defendant knew that this information was not available to the plaintiffs, medical providers and/or to their facilities. In addition, the Defendant is estopped from relying on any statute of limitations because of their intentional concealment of these facts.

48. The Plaintiff had no knowledge that the Defendant was engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by the Defendant, the Plaintiff could not have reasonably discovered the wrongdoing at any time prior. Also, the economics of this fraud should be considered. The Defendant had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on only the Defendant's representations.

## **VII. CLAIMS FOR RELIEF**

### **A. FIRST CLAIM FOR RELIEF**

#### **Negligence**

49. The foregoing paragraphs of this Complaint are realleged and incorporated by

reference.

50. Defendant had a duty to consumers, including Plaintiff, to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling Fosamax.

51. Defendant failed to exercise due care under the circumstances, and therefore breached its duty to Plaintiff.

52. Defendant's negligent acts and omissions, either directly or through its agents, servants, and employees, include, but are not limited to the following:

- a. Manufacturing, producing, promoting, formulating, creating, and/or designing Fosamax without thoroughly and/or adequately testing it;
- b. Not conducting sufficient testing programs to determine whether or not Fosamax was safe for use; in that Defendants herein knew or should have known that Fosamax was unsafe and unfit for use by reason of the dangers to its users.
- c. Selling Fosamax without making proper and sufficient tests to determine the dangers to its users;
- d. Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Fosamax;
- e. Negligently advertising and recommending the use of Fosamax with sufficient knowledge as to its dangerous propensities;
- f. Negligently representing that Fosamax was safe for use for its intended purpose, when, in fact, it was unsafe;

g. Negligently designing Fosamax in a manner which was dangerous to its users;

h. Negligently manufacturing Fosamax in a manner which was dangerous to its users;

i. Negligently producing Fosamax in a manner which was dangerous to its users;

j. Designing, manufacturing, marketing, advertising, distributing, and selling Fosamax to consumers, including Plaintiff, without an adequate warning of the dangerous risks of Fosamax and without proper instructions to avoid harm caused by Fosamax;

k. Improperly concealing and/or misrepresenting information from the Plaintiff, healthcare professionals and/or the FDA, concerning the severity of risks and dangers of Fosamax

l. Failing to exercise due care when advertising and promoting Fosamax; and;

m. Failing to exercise ordinary care by conducting appropriate post-market testing and surveillance of Fosamax.

n. Defendants under-reported, underestimated and downplayed the serious dangers of Fosamax.

53. Although Defendant knew, or should have known, of Fosamax's adverse effects Defendant has continued to negligently manufacture, market, advertise, distribute, and sell Fosamax to consumers, including Plaintiff, so as to maximize sale and profits at the expense

of public health and safety in knowing, conscious and deliberate disregard of the foreseeable harm caused by the subject product.

54. Defendant knew, or should have known, that consumers, including Plaintiff would suffer injuries as a result of Defendant's failure to exercise ordinary care.

55. As a direct and proximate result of the Defendant's negligence and other wrongdoing and actions of Defendant described herein, Plaintiff has sustained serious and permanent injuries, and will continue to suffer injury, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**B. SECOND CLAIM FOR RELIEF**  
**Strict Liability – Failure to Warn**

56. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.

57. Defendant designed, tested, manufactured, marketed, sold and/or distributed Fosamax. As such, it had a duty to warn the using public, including Plaintiff, of the health risks associated with using the subject product.

58. The subject product was under the exclusive control of Defendant and was unaccompanied by appropriate warnings regarding the health risks associated with its use, including osteonecrosis of the jaw. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injury to the consumer. The promotional activities of Defendant further diluted or minimized the warnings given with the product.

59. The subject product was defective and unreasonably dangerous when it left

the possession of the Defendant in that it contained warnings insufficient to alert Plaintiff to the dangerous risks and reactions associated with it, including, but not limited to osteonecrosis of the jaw. Even though Defendant knew or should have known of the risks and reactions associated with the subject product, it still failed to provide warnings that accurately reflected the signs, symptoms, incidence, scope, or severity of these risks

60. Plaintiff used the subject product for its intended purpose, i.e. for the prevention or treatment of osteoporosis.

61. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

62. Plaintiff would not have used Fosamax had Defendant properly disclosed the risks associated with the drug.

63. Defendant, as a manufacturer of pharmaceutical drugs, is held to the level of knowledge of an expert in the field, and further, Defendant had knowledge of the dangerous risks and side effects of the subject product.

64. Plaintiff did not have the same knowledge as Defendant and no adequate warning was communicated to her.

65. Defendant had a continuing duty to warn consumers, including Plaintiff, of the dangers associated with the subject product. By negligently and/or wantonly failing to adequately warn of the dangers of use of the subject product, Defendant breached its duty.

66. Although Defendant knew of the defective nature of the subject product, they continued to design, manufacture, market, and sell it without providing accurate, adequate, and complete warnings concerning its use so as to maximize sales and profits at the expense of the

public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by the subject product.

67. As a direct and proximate result of the Defendant's failure to adequately warn or other wrongdoing and actions of Defendant described herein, Plaintiff has sustained serious and permanent injuries, and will continue to suffer injury, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**C. THIRD CLAIM FOR RELIEF**  
**Strict Liability – Defective Design**

68. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.

69. Defendant is the manufacturer, seller, distributor, marketer, and/or supplier of the subject product, which is defective and unreasonably dangerous to consumers.

70. The subject product was designed, manufactured, sold, distributed, supplied, marketed, and/or promoted by Defendant, and was expected to reach and did reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.

71. The subject product was defective in its design and was unreasonably dangerous in that its foreseeable risks exceeded the benefits associated with its design or formulation.

72. Consumers, including Plaintiff, who have used Fosamax for the prevention or treatment of osteoporosis, have several alternative safer products available to treat this condition.

73. Although Defendant actually knew of the defective nature of the subject

product, it continued to design, manufacture, market, and sell it so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious and deliberate disregard of the foreseeable harm caused by the subject product.

74. As a direct and proximate result of the design defects of the subject product, Plaintiff has sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**D. FOURTH CLAIM FOR RELIEF**  
**Breach of Express Warranty**

75. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.

76. Defendant expressly represented to Plaintiff SHARON REDFORD, other consumers and the medical community that Fosamax was safe and fit for its intended purposes, of merchantable quality, did not produce any dangerous side effects, and was adequately tested.

77. Fosamax does not conform to Defendant's express representations because it is defective and unfit for its intended purpose, i.e. it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.

78. The subject product was defective and unreasonably dangerous when it left the possession of the Defendant in that it contained warnings insufficient to alert Plaintiff to the dangerous risks and reactions associated with it, including, but not limited to osteonecrosis of the jaw.

79. At all relevant times Fosamax did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

80. Plaintiff JANIS GRAHAM, other consumers and the medical community relied upon Defendant's express warranties.

81. As a direct and proximate result of Defendant's express warranties of the subject product, Plaintiff has sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**E. FIFTH CLAIM FOR RELIEF**  
**Breach of Implied Warranty**

82. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.

83. Defendant designed, tested, manufactured, marketed, sold and/or distributed Fosamax.

84. At all relevant times, Defendant knew of the use for which Fosamax was intended and impliedly warranted the product to be safe and fit for such use.

85. Defendant was aware that consumers, including Plaintiff, would use Fosamax for the prevention or treatment of osteoporosis, and knew, or recklessly disregarded, that consumers, including Plaintiff, and the medical community relied upon its judgment and sensibility to only sell Fosamax if it was safe and fit for its intended use.

86. Defendant herein breached its implied warranty to consumers, including



Plaintiff; Fosamax was not safe or fit for its intended use.

87. Consumers, including Plaintiff, and the medical community reasonably relied upon Defendant's implied warranty for Fosamax.

88. Fosamax reached Plaintiff without substantial change in the condition in which it was manufactured and sold by Defendant.

89. As a direct and proximate result of Defendant's implied warranties of the subject product, Plaintiff has sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**F. SIXTH CLAIM FOR RELIEF**

**Fraud**

90. The foregoing paragraphs of this Complaint are realleged and incorporated by reference

91. Defendant falsely and fraudulently represented to the medical community, and to the Plaintiff and the public in general, that Fosamax had been tested and found to be safe and effective for the prevention and treatment of osteoporosis

92. Defendant knew, or should have known, that its representations were false yet it willfully, wantonly and recklessly disregarded its obligation to provide truthful representations regarding the safety and risks of Fosamax to consumers, including Plaintiff, and the medical community

93. Defendant's representations were made with the intent of defrauding and

deceiving consumers, including Plaintiff, and the medical community, with the intent of encouraging and inducing sales of Fosamax.

94. Defendant knowingly, consciously, and deliberately placed its financial gain above the rights and safety of Plaintiff and other consumers.

95. Defendant's fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

96. Plaintiff was unaware of the falsity of Defendant's representations and reasonably relied upon Defendant's representations, thereby developing osteonecrosis of the jaw.

97. As a direct and proximate result of Defendant's fraudulent misrepresentation of the subject product, Plaintiff has sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**G. SEVENTH CLAIM FOR RELIEF**  
**Fraudulent Misrepresentation and/or Concealment**

98. Plaintiffs reallege the above paragraphs.

99. Defendant fraudulently concealed information with respect to FOSAMAX in the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters and regulatory submissions that FOSAMAX was safe and fraudulently withheld and concealed information about the substantial risks of using FOSAMAX; and

b. Defendant represented FOSAMAX was safer than other

alternative medications and fraudulently concealed information which demonstrated that FOSAMAX was not safer than alternatives available on the market.

**H. EIGHTH CLAIM FOR RELIEF**  
**Negligence Per Se**

100. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

101. Defendants have an obligation not to violate the law.

102. Defendants have violated the Federal Food, Drug and Cosmetic Act, 21, U.S.C. 301, *et Seq.*, related amendments and codes and federal regulations promulgated thereunder, and other applicable state and federal laws.

103. Plaintiff, as a purchaser and consumer of Fosamax, is within the class of persons that statutes described above are designed to protect.

104. Injury due to false, misleading and/or reckless advertising and promotion, and misbranding, misleading products and as otherwise set forth in this complaint, is the specific type of harm these statutes are designed to prevent.

105. Defendants are responsible to plaintiff for injuries incurred for their violations of the statutes described above under the doctrine of negligence pro se.

106. As a direct and proximate result of the negligence and negligence per se of the defendants and each one individually and as a result of the defendants' actions and/or inactions as set forth in this complaint, Plaintiff was caused to suffer the serious and dangerous side effect of osteonecrosis, as well as other severe and personal injuries which

are permanent and lasting in nature, including but not limited to physical pain and mental anguish, diminished enjoyment of life, and any and all life complications such as Plaintiff's need for lifelong medical treatment, monitoring and/or medications, and to incur related expenses, including but not limited to, loss of earnings and/or other costs as the proof will demonstrate, and the plaintiff demands all damages to which the plaintiff is entitled under the law in an amount deemed fair and reasonable.

**I. NINTH CLAIM FOR RELIEF**  
**Unjust Enrichment**

107 Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein.

108 At all times relevant to this action, Defendants were the manufacturers, sellers, and/or suppliers of FOSAMAX.

109 Plaintiff paid for FOSAMAX for the purpose of managing her pain safely and effectively.

110 Defendants have accepted payment from Plaintiff for the purchase of FOSAMAX

111 Plaintiff did not receive the safe and effective pharmaceutical product for which she paid.

112 It is inequitable and unjust for Defendants to retain this money because the Plaintiff did not in fact receive the product Defendant represented FOSAMAX to be.

WHEREFORE, Plaintiffs demand judgment against Defendants and seeks equitable relief, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

**J. TENTH CLAIM FOR RELIEF**  
**Loss of Consortium**

113. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.

114. Plaintiff Janis Graham's spouse, John Graham was at all times relevant herein the husband of, and as such, lives and cohabits with Plaintiff Janis Graham.

115. By reason of the foregoing, Plaintiff's spouse has necessarily paid and has become liable to pay for medical aid, treatment, attendance, and for medications, and will necessarily incur further expenses of a similar nature in the future.

116. By reason of the foregoing, Plaintiff's spouse has been caused, presently and in the future the loss of his wife's companionship, services, society and the ability of said Plaintiff's spouse in said respects has been impaired, and depreciated, and the marital association between husband and wife has been altered, and as such the Plaintiff's spouse has been caused great mental anguish and suffering.

117. Plaintiffs demand judgment against each Defendant individually and/or jointly for compensatory damages and punitive damages together with interest, costs of suit and attorneys' fees and for such other relief as the Court deems proper

**VII. DEMAND FOR JURY TRIAL**

Plaintiffs demand a trial by jury on all claims so triable in this action.

**VIII. PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs request the following relief:

1. General damages in excess of the jurisdictional amount of this Court;

2. Physical Pain and Suffering;
3. Mental Anguish;
4. Loss of Consortium;
5. Past and Future Medical and Counseling Expenses;
6. Disgorgement of profits;
7. Punitive and exemplary damages;
8. Pre-judgment and post-judgment interest as provided by law;
9. Recovery of Plaintiffs' costs including, but not limited to, discretionary Court costs of these causes, and those costs available under the law, as well as expert fees and attorneys' fees and expenses, and costs of this action; and
10. Such other and further relief as the Court deems just and proper.

Dated: July 30, 2007

Respectfully submitted,

THE LANIER LAW FIRM, PC

By: 

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